



9052 '98 NOV 24 P2:47



November 15, 1998

RECEIVED  
11/16/98

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) The vitamin E in wheat germ oil supports the cell membranes of all tissue in the human body, especially those in the nervous system. Vitamin E is an anti-oxidant that protects and repair cell membranes, especially those of nerve cells, from damage by the highly reactive oxygen compounds known as free radicals.\*
- (2) The vitamin E in wheat germ oil supports the proper functioning of the cardiovascular system. Vitamin E in wheat germ oil protects lipoproteins in the blood from damage by free radical oxygen and in doing so helps prevent the buildup of fatty deposits in the cell wall of the cardiovascular system.\*
- (3) The vitamin E in wheat germ oil maintains eye lens transparency. Vitamin E can help preserve the clarity of the eye lens.\*
- (4) The vitamin E in wheat germ oil protects material in the cell nucleus from damaging free radicals. It also detoxifies singlet oxygen and peroxy radicals, thus protecting cell membranes, including those adjacent to nucleic material.\*

These statements are made for a dietary supplement containing wheat germ oil. The name of the product is Wheat Germ Oil™.

97S - 0162



STANDARD PROCESS INC. • 1200 WEST ROYAL LEE DRIVE • PALMYRA, WI 53156 • 414-495-2122 • FAX 414-495-2512 • 1-800-848-5061

62273  
LET 2646





The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

